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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,201	03/03/2004	Kjell Goran Erik Backstrom	06275-004003	4197
26161	7590	02/03/2006	EXAMINER	
FISH & RICHARDSON PC			LUKTON, DAVID	
P.O. BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

1654

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/792,201

Applicant(s)

BACKSTROM ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicants' election of Group I is acknowledged.

Also acknowledged are the elected species (the peptide is insulin, the surfactant is sodium caprate and the non-hygroscopic additive is mannitol).

Claims 21-40 are now pending. Claims 21-37 are examined in this Office action; claims 38-40 are withdrawn from consideration.



Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of 5,747,445 or claim 1 of 5,518,998 or claim 1 of USP 6,632,456 or claim 1 of 6,165,976 or claim 2 of USP 5,506,203 or claim 1 of USP 5,518,998 or claim 54 of USP 6794357. In addition, claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over any of claims 1 or 30-38 of USP 6,524,557. Although the conflicting claims are not identical, they are not patentably distinct from each other. The genera of compositions overlap in each case.

In addition, claim 21 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 69 of copending application 10/224522.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on

this ground provided the conflicting application or patent is shown to be commonly owned with this application
See 37 CFR 1.78(d).



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 requires that at least 50% of the mass of (A) and (B) consists of particles that have a diameter which is less than 10 microns. For this description taken by itself there is probably adequate descriptive support. But the claim also requires that the carrier particles have a diameter of at least 20 microns. The claim thus sets up a dichotomy between the particle size of the peptide and surfactants (on the one hand) and the particle size of the carrier (on the other hand). There appears to be no descriptive support for carrier particles having a diameter of at least 20 microns, but even if support for such a subgenus does exist somewhere, there is certainly no descriptive support for carrier particles having a diameter of at least 20 microns at the same time that the particle size of components (A) and (B) is limited to 10 microns.



- References "BCC", "BDD", "BEE", "BFF", etc. have been stricken from the IDS. These are neither patents nor published patent applications. Accordingly, these documents should be listed in the "other documents" section. In addition, it would be preferable to cite the corresponding PG Pub document, or issued patent. However, citing redundant documents would appear to serve no purpose. For example, it is not clear what is gained by listing application 10/224522 along with the published 10/224522 (i.e., US 2003/0064928).
- Those Japanese patents which were stricken from the IDS were so treated because of the absence of a translation.
- Reference "EE" was stricken from the IDS because only the first two pages of the article were received.
- The remaining documents that were stricken from the IDS were so treated because they were not received, and were not present in the parent file

. . .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



**DAVID LUKTON
PATENT EXAMINER
GROUP 1800**